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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,853	08/13/2003	Randall V. Sparer	P-10998.00	9178

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/640,853	SPARER ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/14/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/14/2007 has been entered.

Amendment entered

The amendments to the claims filed 09/14/2007 have been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (US 2002/0082679 A1).

Sirhan teaches a luminal prosthesis that can be in the form of a stent, the stent can further contain a rate-controlling element formed from polymers including cellulose acetate butyrate (CAB), polyethylene vinyl acetate (PEVA), polyurethane,

polycarbonates, polymethylmethacrylate and the like and mixtures and combinations thereof, the rate controlling element provides for a controlled release of at least one active ingredient that can be contained within the element. See abstract, [0046]-[0050],[0053] and claims 1,18,74-76,80-82,112-118 and 126. The active ingredient included numerous therapeutics including dexamethasone, azatioprine and prednisone, all of the above active ingredients are also disclosed as active ingredients within applicants own specification. See claim 18 and [0030]. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10,5 or 3 $J^{1/2}cm^{3/2}$, Sirhan teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that the miscible polymer blend initially provides a barrier to permeation, this limitation is met, since Sirhan teaches the use of the same polymers in a mixture with the active agent contained within that the polymer it will provide the same barrier to permeation since the polymers are the same then their release properties will inherently be the same. Regarding the limitations that at least

one polymer has a higher diffusivity and one lower then the target diffusivity, this limitation is met since it is inherent that the diffusivity for the polymer films (also their TG diffusivities) and the active agent would be the same as the applicants since the polymeric films and the active agents are the same. Regarding the limitation on swellability for the polymer blend which is no more than 10% by volume, this limitation is met, because Sirhan teaches the use of polymeric films within the scope of the applicants claims therefore it is inherent that since the polymer films are the same they will have the same swellability by volume. Regarding claims 71-74 it is inherent that a stent, being an implantable device, would deliver an active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations in claims 75-78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Sirhan who teaches a method to make the same polymer blend as claimed by applicant, the blend incorporated a bioactive agent, therefore the polymer blend would control the delivery of the bioactive agent in the same way as applicants claims since the same composition will inherently have the same properties.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252).

Hossainy teaches a coating for stents and a method for forming the coated stent having a film forming biocompatible polymer coating in which different polymers may be used for different layers (polyurethanes, polyamides, polyesters, polymethacrylates

polyolefins, ethylene methyl methacrylate copolymers various hydrophilic celluloses and many other hydrophobic and hydrophilic polymers were specifically listed) in which the top coat (either a film or matrix) can be used to deliver therapeutic and pharmaceutical agents (including fluorouracil which is disclosed as an active ingredient within applicants own specification). See col 1 lin 6-9, col 2 lin 9-19, col 4 lin 15-col 5 lin 38, col 7 lin 5-11, lin 56-col 8 lin 35, col 9 lin 20-25, fig. 6 and 7. See col 7 lin 18-55. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10,5 or 3 $J^{1/2}cm^{3/2}$, Hossainy teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that the miscible polymer blend initially provides a barrier to permeation, this limitation is met, since Hossainy detailed the use of a top coating to delay release of the pharmaceutical agent. Regarding the limitations that at least one polymer has a higher diffusivity and one lower then the target diffusivity is met since the target diffusivity is determined by the preselected time for delivery and the preselected critical dimension of the polymer which

is taught by Hossainy; it is inherent that the diffusivity for the polymer films (also their TG diffusivities) and the active agent would be the same as the applicants since the polymeric films and the active agents are the same. See col 7 lin 18-55, fig. 6 and 7. Regarding the limitation on swellability for the polymer blend which is no more than 10% by volume, this limitation is met, because Hossainy teaches the use of polymeric films within the scope of the applicants claims therefore it is inherent that since the polymer films are the same they will have the same swellability by volume. Regarding claims 71-74 it is inherent that a stent, being an implantable device, would deliver an active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations in claims 75-78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Hossainy who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active agent in the same way as applicants newly entered claims.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483).

Whitbourne teaches a coating for biomedical devices (including stents) and the method to make the coatings in which the coating is a blend of a stabilizing polymer and an active agent comprised of a hydrophilic polymer (the blends can include the following: polyurethanes, acrylic polymers, methacrylic polymers, vinyl acetal polymers,

polyethers, PVP, epoxy polymers, several hydrophilic celluloses and numerous other stabilizing and hydrophilic polymers/copolymers) the coating also comprises a bio-active agent contained within (including thymol which is disclosed as an active ingredient within applicants own specification). See col 1 lin 5-12, lin 65-col 2 lin 24, lin 31-38, lin 43-47, col 3 lin 21-59, col 4 lin 13-36, col 5 lin 28, lin 41-46, col 7 lin 15-17, lin 55-56, col 9 lin 29-32, 50-54 and claim 17. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10,5 or 3 $J^{1/2}cm^{3/2}$, Sirhan teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that "the miscible polymer blend initially provides a barrier to permeation" this limitation is met, since Whitbourne discuses a time-release effect of the active ingredient attributable to the interaction of the bioactive agents with the stabilizing polymer. See col 3 lin 56-59. Regarding the limitation that the swellability for the polymer blend is no more than 10% by volume, this limitation is met, because Whitbourne discusses the swellability of the hydrophilic polymer in the composition,

while the patent discussed the swellability in terms of weight not volume it is inherent that by blending with a non-swelling polymer the blend could have swelling of no greater than 10% of its own volume, also since the polymers are the same so will be their physical properties such as swelling. See col 5 lin 1-12. Regarding the limitation that at least one polymer has a higher diffusivity and one lower then the target diffusivity, this is considered inherent by the examiner (see above). Regarding claims 71-74 it is inherent that a stent being an implantable device would deliver any active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations in claims 75-78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Hossainy who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active agent in the same way as applicants newly entered claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1).

Sirhan is disclosed above. The Sirhan patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Sirhan encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081] within Perez. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to

form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252).

Hossainy is disclosed above. The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Hossainy is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Hossainy encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081]. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483).

Whitbourne is disclosed above. The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Whitbourne is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Whitbourne encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081]. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Response to Arguments

Applicant's arguments filed 09/14/2007 have been fully considered but they are not persuasive.

Applicants asserts that Hossainy and Whitbourne fails explicitly or inherently teach each and every element of the amended claims which recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order to form a miscible blend particularly suited for tunable delivery of an active agent. Applicants surmise that the examiner is not considering the fact that applicant's claims are drawn to methods by which the coatings and miscible polymer blends are formed. Thus applicants assert there is a conscience and deliberate method in the selection process of choosing the polymers.

The relevance of these assertions is unclear. It appears as though applicants are claiming an abstract idea, applicants claims are drawn to a method of producing an active agent delivery system. Applicant's claims do not actually recite selecting two polymers based on their solubility parameters, rather the claims recite that a first miscible polymer is provided and then selecting another second polymer and combining the two, forming a miscible polymer blend. The recitation of the solubility parameter does not actually mention that the two polymers are selected based on their solubility parameter it is merely recites a physical property of the two polymers. The selection of

the second polymer could be made by numerous means known to those of ordinary skill in the art. Therefore in order to anticipate applicants claimed invention the examiner only has to meet a method of making an active delivery agent system with applicants claimed ingredients. The solubility parameters as stated above are in inherent property of the ingredients, therefore their recitation, as a claim limitation does not preclude any reference that discloses those same ingredients. Also applicant's argument that the claimed invention is in undiscovered property is also not found persuasive. As disclosed above within the Perez reference it was already understood in the art at the time of applicants claimed invention to use solubility parameters to predict if polymers would be miscible with each other. Essentially it appears as though applicants are claiming a method to produce a known material by methods already well known in the art to be common scientific knowledge. As cited above it appears as though applicants are claiming a method to produce a material based upon the ingredients properties which may have been undiscovered or unknown. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER